

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ELAN CORPORATION, PLC and	)	
ELAN PHARMA INTERNATIONAL LTD.,	)	
	)	
Plaintiffs,	)	C.A. No. 07-736 (SLR)
	)	
v.	)	
	)	
BARR LABORATORIES, INC.,	)	
	)	
Defendant.	)	

**PLAINTIFFS' REPLY TO DEFENDANT  
BARR LABORATORIES, INC.'S COUNTERCLAIMS**

Plaintiffs Elan Corporation, plc and Elan Pharma International Ltd. (collectively "Elan"), for their Reply to the numbered paragraphs of the Counterclaims of Defendant Barr Laboratories, Inc. ("Barr"), hereby state as follows:

**PARTIES**

1. Admitted, upon information and belief.
2. Admitted.
3. Admitted.
4. Admitted.
5. Admitted.

**JURISDICTION AND VENUE**

6. Admitted that Barr purports to state declaratory judgment counterclaims that arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Admitted that Barr purports to base subject matter jurisdiction on the statutes listed in Paragraph 6, assuming that Barr intended to refer to

28 U.S.C. § 2202. Plaintiffs do not contest that subject matter jurisdiction exists. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 6.

7. Plaintiffs do not contest personal jurisdiction in Delaware for this action.

8. The allegations contained in Paragraph 8 of Barr's Counterclaims are legal conclusions to which no response is required. Plaintiffs do not contest venue in this Court for this action.

#### BACKGROUND

9. The allegations contained in Paragraph 9 of Barr's Counterclaims are legal conclusions to which no response is required.

10. The allegations contained in Paragraph 10 of Barr's Counterclaims are legal conclusions to which no response is required.

11. The allegations contained in Paragraph 11 of Barr's Counterclaims are legal conclusions to which no response is required.

12. The allegations contained in Paragraph 12 of Barr's Counterclaims are legal conclusions to which no response is required.

13. The allegations contained in Paragraph 13 of Barr's Counterclaims are legal conclusions to which no response is required.

14. The allegations contained in Paragraph 14 of Barr's Counterclaims are legal conclusions to which no response is required.

15. The allegations contained in Paragraph 15 of Barr's Counterclaims are legal conclusions to which no response is required.

16. The allegations contained in Paragraph 16 of Barr's Counterclaims are legal conclusions to which no response is required.

17. The allegations contained in Paragraph 17 of Barr's Counterclaims are legal conclusions to which no response is required.

18. The allegations contained in Paragraph 18 of Barr's Counterclaims are legal conclusions to which no response is required.

19. The allegations contained in Paragraph 19 of Barr's Counterclaims are legal conclusions to which no response is required.

20. The allegations contained in Paragraph 20 of Barr's Counterclaims are legal conclusions to which no response is required.

21. The allegations contained in Paragraph 21 of Barr's Counterclaims are legal conclusions to which no response is required.

22. The allegations contained in Paragraph 22 of Barr's Counterclaims are legal conclusions to which no response is required.

23. The allegations contained in Paragraph 23 of Barr's Counterclaims are legal conclusions to which no response is required.

24. Admitted that Elan owns United States Patent Nos. 6,228,398 ("the '398 patent") and 6,730,325 ("the '325 patent").

25. Admitted, upon information and belief, that Barr submitted abbreviated new drug application ("ANDA") No. 79-091 to the Food and Drug Administration ("FDA"), with a Paragraph IV Certification, to engage in the manufacture, use, or sale of 5 mg, 10 mg, 15 mg and 20 mg of dexamethylphenidate hydrochloride extended release capsules ("Barr's Proposed Products").

26. Plaintiffs are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 26.

27. Admitted that Barr sent Elan a notice letter relating to ANDA No. 79-091 dated October 5, 2007 offering limited confidential access to certain parts of Barr's ANDA, but denied that the letter contained a detailed factual and legal statement as to why the '398 and '325 patents were invalid, unenforceable and/or not infringed by Barr's Proposed Products. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 27.

28. Admitted that Plaintiffs filed this lawsuit on November 16, 2007 alleging that Barr's submission of ANDA 79-091 to the FDA constitutes infringement of the '398 and '325 patents and that Barr's commercial manufacture, use, offer for sale or sale of Barr's Proposed Products would infringe the '398 and '325 patents, and that Barr was served with the Complaint on November 19, 2007.

29. Denied.

#### FIRST COUNTERCLAIM

30. Plaintiffs repeat and incorporate their reply to Paragraphs 1-29.

31. Admitted that Barr purports to state a counterclaim that arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and that Barr seeks a declaration that claims of the '398 patent are invalid, but denied that there is any factual or legal basis for this counterclaim.

32. Admitted that Plaintiffs allege the '398 patent was duly and legally issued by the United States Patent and Trademark Office and has been infringed by Barr and that Barr has denied those allegations, but denied that there is any factual or legal basis for Barr's denials.

33. The allegations contained in Paragraph 33 of Barr's Counterclaims are legal conclusions to which no response is required.

34. Denied.

SECOND COUNTERCLAIM

35. Plaintiffs repeat and incorporate their reply to Paragraphs 1-29.

36. Admitted that Barr purports to state a counterclaim that arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and that Barr seeks a declaration that claims of the '325 patent are invalid, but denied that there is any factual or legal basis for this counterclaim.

37. Admitted that Plaintiffs allege the '325 patent was duly and legally issued by the United States Patent and Trademark Office and has been infringed by Barr and that Barr has denied those allegations, but denied that there is any factual or legal basis for Barr's denials.

38. The allegations contained in Paragraph 38 of Barr's Counterclaims are legal conclusions to which no response is required.

39. Denied.

THIRD COUNTERCLAIM

40. Plaintiffs repeat and incorporate their reply to Paragraphs 1-29.

41. Admitted that Barr purports to state a counterclaim that arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and that Barr seeks a declaration that the manufacture, use, sale, or offer for sale of Barr's Proposed Products do not and will not infringe any claims of the '398 patent, but denied that there is any factual or legal basis for this counterclaim.

42. The allegations contained in Paragraph 42 of Barr's Counterclaims are legal conclusions to which no response is required.

43. Denied.

44. Denied.

FOURTH COUNTERCLAIM

45. Plaintiffs repeat and incorporate their reply to Paragraphs 1-29.

46. Admitted that Barr purports to state a counterclaim that arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and that Barr seeks a declaration that the manufacture, use, sale, or offer for sale of Barr's Proposed Products do not and will not infringe any claims of the '325 patent, but denied that there is any factual or legal basis for this counterclaim.

47. The allegations contained in Paragraph 47 of Barr's Counterclaims are legal conclusions to which no response is required.

48. Denied.

49. Denied.

REPLY TO BARR'S PRAYER FOR RELIEF

WHEREFORE, Plaintiffs deny that Barr is entitled to any relief, either as prayed for in its Counterclaims or otherwise.

Plaintiffs further deny each allegation in Barr's Counterclaims that was not specifically admitted, denied, or otherwise responded to in this Reply to Defendant Barr Laboratories, Inc.'s Counterclaims.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Richard J. Bauer*

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Elan Pharma International Ltd*

February 1, 2008  
1419080

**CERTIFICATE OF SERVICE**

I hereby certify that on February 1, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

John C. Phillips, Jr., Esquire  
Brian E. Farnan, Esquire  
PHILLIPS, GOLDMAN & SPENCE, P.A.

I further certify that I caused to be served copies of the foregoing document on February 1, 2008 upon the following in the manner indicated:

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